Remarks

Introduction

Claims 19, 20, and 22-25 were pending. By way of this response, the specification and claims 19, 23, and 24 have been amended and claim 25 has been cancelled without prejudice. Support for the amendments to the specification and the claims can be found in the application as originally filed, and care has been taken to avoid adding new matter. For example, support for the amendments to the specification can be found in U.S. Application No. 09/371,354. Support for the amendments to the claims can be found at least at page 4, lines 4-14; page 4, line 32 to page 5, line 8; page 9, lines 2-6; page 13, lines 11-12; and page 21, lines 26-31. Accordingly, claims 19, 20, and 22-24 are currently pending.

Objections

The specification has been objected to for not having page numbers.

Applicant submits herewith a substitute specification (marked up and clean copies) which properly include page numbers.

In view of the above, applicant submits that the specification is in proper form and requests that this objection regarding page numbers be withdrawn.

Rejection Under 35 U.S.C. § 101

Claim 23 has been rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 13 and 14 of U.S. Patent No. 6,767,544 (the '544 patent).

Claim 23 has been amended to include the subject matter of claim 25, which was not rejected under 35 U.S.C. § 101.

In view of the above, applicant submits that the present claims satisfy the requirements of 35 U.S.C. § 101, and respectfully requests that the rejection of the present claims based on this statutory provision be withdrawn.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 19, 20, and 22 have been rejected under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement. In particular, the Office Action states that applicant has not specifically identified where in the specification the written support for the concept can be found.

Applicant traverses the rejection.

As stated previously, the subject matter regarding eluting stents was disclosed in U.S. Application No. 09/371,354, which was incorporated by reference into the specification of the above-identified application at the time of filing the above-identified application.

Nevertheless, by way of the enclosed substitute specification, applicant has amended the paragraph beginning at page 22, line 5 to include the paragraph beginning at page 26, line 21 of U.S. Application No. 09/371,354. Since U.S. Application No. 09/371,354 was incorporated by reference at the time of filing the above-identified application, the amendments to the specification of the above-identified application do not introduce new matter.

In response to the rejection of claims 19, 20, and 22, applicant submits that the subject matter of eluting stents are disclosed at page 22, lines 13-16.

In view of the above, applicant submits that the subject matter of the present claims, and claims 19, 20, and 22 in

particular, satisfy the written description requirements of 35 U.S.C. § 112, first paragraph, and respectfully requests that the rejection of the present claims based on this statutory provision be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 19, 20, and 22-25 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Vigil et al. (U.S. Patent No. 6,102,904; hereinafter Vigil) in view of Schramm et al. (U.S. Patent No. 6,121,296; hereinafter Schramm) and Rappuoli et al. (1997; hereinafter Rappuoli).

In particular, the Office Action acknowledges that Vigil does not teach a botulinum toxin (Office Action, page 4, last sentence of third paragraph). In contrast, Vigil teaches the use of cytotoxic agents such as pseudomonas exotoxin and Ricin A toxin.

The Office Action further states that Schramm discloses ADP-ribosylation toxins that include pseudomona enterotoxin and botulinum toxin.

In addition, the Office Action states that Rappuoli discloses botulinum C2 toxins and the botulinum C3 ADP-ribosyltransferase.

The Office Actions states that it would be obvious to a person of ordinary skill in the art to modify the composition of Vigil to substitute the botulinum toxin of Rappuoli for the toxin disclosed by Vigil since Schramm teaches both pseudomonas toxin and botulinum toxin function as ADP-ribosylating toxins, and that substitution of one function equivalent for another is routine in the art.

Applicant has amended the claims as set forth above and traverses the rejection as it relates to the present claims.

Applicant submits that the combination of Vigil, Schramm and Rappuoli does not disclose, teach, or suggest the present invention. For example, the combination of Vigil, Schramm, and Rappuoli does not disclose, teach, or even suggest a stent or angioplasty balloon with a therapeutically effective amount of a botulinum neurotoxin, as recited in the present claims.

As discussed above, Vigil discloses the use of anti-proliferative agents or cytotoxic agents that kill rapidly dividing cells (column 3, lines 40-41). Vigil does not disclose, teach, or even suggest the use of any toxins that are not cytotoxic, let alone any toxins produced from Clostridial bacteria, such as botulinum neurotoxin. Vigil is directed to delivery of anti-proliferative agents to treat or inhibit stenoses, including restenosis.

Schramm is directed to solving the problem of developing a method of preventing purine and pyrimidine salvage by parasitic organisms (column 2, lines 19-21). Schramm indicates that several different bacterial toxins may disrupt cellular function by using NAD+ and transferring ADP-ribose to regulate guanine nucleotide binding proteins when an individual is infected by bacteria which produce such toxins (column 2, lines 3-10). In short, Schramm discloses chemical compounds which may be effective in interfering with the cellular disruption caused by bacterial infection. Schramm does not disclose, teach, or even suggest therapeutic use of any toxin, let alone such use of a Clostridial neurotoxin, such as a botulinum neurotoxin. For example, Schramm does not disclose, teach, or even suggest a therapeutically effective amount of a botulinum neurotoxin, as recited in the present claims.

Rappuoli et al. discloses general information regarding C2 toxin. Rappuoli discloses that C2 toxin is an ADP-

ribosyltransferase that effects the actin cytoskeleton, such as by destroy the microfilament network and depolymerizing actin filaments. Rappuoli discloses that C2 toxin is not a clostridial neurotoxin. Therefore, Rappuoli discloses that C2 toxin is not a botulinum neurotoxin, as recited in the present claims.

Applicant submits that the combination of Vigil, Schramm, and Rappuoli do not disclose, teach, or suggest all of the elements recited in the present claims, and applicant submits that a person of ordinary skill in the art would not be motivated to combine the deficient teachings, let alone do so and obtain the presently claimed invention. Therefore, the rejection of the present claims under 35 U.S.C. § 103 cannot be properly maintained.

As discussed above, Vigil does not disclose or even suggest a botulinum neurotoxin, as recited in the present claims. In contrast, Vigil discloses cytotoxic agents that are different and distinct from botulinum neurotoxins. For example, botulinum neurotoxins are not cytotoxic agents. Furthermore, Vigil does not disclose or even suggest a stent or balloon that has a therapeutically effective amount of a botulinum neurotoxin.

Schramm fails to provide the deficiencies apparent in Vigil. For example, Schramm fails to disclose, teach, or even suggest a therapeutically effective amount of a botulinum neurotoxin, let alone such a therapeutically effective amount in combination with a stent or angioplasty balloon. In contrast, Schramm discloses that botulinum neurotoxin is not therapeutic and is actually a cause of infection or disease.

Similarly, Rappuoli does not provide the deficiencies apparent in each of Vigil and Schramm. For example, Rappuoli does not disclose, teach, or even suggest a therapeutically

effective amount of a botulinum neurotoxin, as recited in the present claims. In contrast, Rappuoli discloses C2 toxins that interfere with actin cytoskeletons, and that C2 toxin is different and distinct from botulinum neurotoxin since the C2 toxin is not a clostridial neurotoxin.

Thus, applicant submits that the combination of references, including Vigil, Schramm, and Rappuoli, fails to disclose, teach, or even suggest all of the elements of the present claims. For example, the combination does not disclose any therapeutically effective amount of a botulinum neurotoxin, as recited in the present claims.

In addition, applicant submits that a person of ordinary skill in the art would not be motivated to combine the teachings of Vigil, Schramm, and Rappuoli, let alone do so and obtain the presently claimed invention.

Applicant submits that Vigil, Schramm, and Rappuoli are directed to solving different and distinct problems. For example, Vigil is directed to new devices to administer cytotoxic agents to treat or inhibit stenoses; Schramm is directed to new compounds that treat infections or disease caused by bacterial toxins, such as botulinum toxins; and Rappuoli is directed to describing the effects of C2 toxin on cellular actin cytoskeletons. The teachings of the references are so different that a person of ordinary skill in the art would not be motivated to combine the teachings or even consider such teachings since the references are directed to solving entirely different problems. Thus, applicant submits that a person of ordinary skill in the art given the teachings of Vigil would not be motivated to use or even combine the teachings of a reference, such as Schramm or Rappuoli, that are directed to completely different and distinct problems from the problem

addressed by Vigil. This lack of a motivation is particularly clear since Schramm does not disclose any therapeutic use whatsoever of a botulinum neurotoxin, and in contrast teaches that botulinum neurotoxin is the cause of disease, and since Rappuoli does not disclose any therapeutic use of a botulinum neurotoxin, as recited in the present claims.

In view of the above, applicant submits that the present claims, that is claims 19, 20, and 22-24, are unobvious from and patentable over Vigil, Schramm, and Rappuoli, taken alone or in any combination, under 35 U.S.C. § 103.

Conclusion

In conclusion, applicant has shown that the present specification is in proper form, that the present claims are not subject to double patenting, satisfy the requirements of 35 U.S.C. § 112, and are unobvious from and patentable over the prior art under 35 U.S.C. § 103. Therefore, applicant submits that the present claims, that is claims 19, 20, and 22-24, are allowable. Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Respectfully submitted,

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Attachments:
Substitute Specification with markings
Clean version of substitute specification
Statement that substitute specification includes no new matter
DECLARATION UNDER MPEP § 608.01(p)